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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

March 2, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Moshko Fuchs
President
Ocuserv Instruments, Inc.
147 – 39 175th Street
Jamaica, New York 11434

Ref: NYK-2004-07

Dear Mr. Fuchs:

During an inspection of your firm located in Jamaica, New York, conducted during the dates of January 13, 14 & 23, 2004, our investigator determined that your firm manufactures medical devices under the brand names of "***Ultrasonic Imaging Systems (a/k/a) Autoscan DB 3000 & DB 3000C Biometric Rulers, Ophthalmic A-Scan Systems***". These devices are software driven and measure the axial length of the eye, anterior chamber depth, and lens thickness plus calculate the power of an intraocular lens that replaces the eye's natural lens after cataract surgery. These are devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The devices identified as the Ultrasonic Imaging Systems (aka) Autoscan DB 3000 & DB 3000C Biometric Rulers Ophthalmic A-Scan Systems are adulterated within the meaning of section 501(h) of the Act, in that, the methods used in, or the facilities or controls used for the manufacturing, packaging, storage, or installation are not in conformance with good manufacturing practices, as specified in Title 21, ***Code of Federal Regulations (CFR)***, Part 820, Quality System Regulations for Medical Devices, as follows:

1) Failure to document process validation results and activities as required by 21 CFR 820.75(a).

Specifically, the software transfer process using your firm's ChipMaster 3000 (V.2.61) programmer has not been validated to assure that it is capable of reproducing and completely copying the master software program onto a blank [redacted] chip that will subsequently be installed into the finished device, an Ophthalmic Autoscan DB 3000C System.

2) Failure to establish and maintain an adequately written Device Master Record (DMR) as required by 21 CFR 820.181.

Specifically, your firm has an incomplete DMR for the Autoscan DB 3000C Biometric Ruler, Ophthalmic A-Scan System in that it consists only of device drawings and lacks any other directives such as: component specifications; production process specifications and methods; quality assurance procedures; packaging and labeling specifications; and installation, maintenance and servicing procedures.

3) Failure to establish the appropriate responsibility, authority and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform tasks as required by 21 CFR 820.20(b)(1).

Specifically, your firm's quality system does not address responsibility and authority for the following: overseeing device production, control and maintenance of the quality system, finished device testing, device software validation, equipment calibration, incoming raw material inspections, approving and implementing corrective and preventative actions and the handling of consumer complaints.

4) Failure to establish, maintain and implement procedures for finished device acceptance as required by 21 CFR 820.80(d).

Specifically, it is required that all finished devices undergo a 48 hour burn in test, but this test was not documented as part of the final device acceptance record.

5) Failure to establish, maintain and implement procedures for acceptance of incoming products as required by 21 CFR 820.80(b).

Specifically, there are no records of inspection to demonstrate that the following components were tested or inspected prior to final assembly into the finished device: LCD's, printed circuit boards, transducers, metal panels, transformers, and main circuit boards.

6) Failure to establish procedures for quality audits and to conduct such audits so as to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22.

Specifically, your firm does not have a written procedure for conducting quality audits of the quality system at defined intervals (identifying audit schedules), and a requirement that quality audits be conducted by individuals who do not have direct responsibility for the matter being audited. Further, there is no requirement to have the management representative maintain and review the quality audit report, conduct re-audits of the problem areas, and implement corrective actions for those problem areas.

7) Failure to ensure that manufacturing equipment is routinely calibrated, inspected, checked and maintained as required by 21 CFR 820.72(a) & (b).

Specifically, on 01/14/2004, it was noted that an oscilloscope (Serial #B013072), displayed a calibration sticker which revealed the last calibration date of 07/02/99 although the unit should have been calibrated on a yearly basis. Further, the oscilloscope was used in the repair department to perform voltage and safety tests and no further action was taken to evaluate whether there was any adverse effect on the device's quality.

8) Failure to establish and maintain instructions and procedures for performing and verifying that servicing meets the specified requirements as required by 21 CFR 820.200(a).

Specifically, no written procedures were established directing the maintenance of service records. Two (2) Biometric Rulers (DB – 3000C / Serial #4030721090 & DB – 3000 / Serial #3104102) were returned to Ocuserv Instruments, Inc. from customers for servicing, but there were no service records containing information such as the following: device name, control number, service date, servicing individual and the test date.

9) Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a).

10) Procedures for implementing corrective and preventative actions (CAPA) were not established and maintained as required by 21 CFR 820.100(a).

11) Failure to establish and maintain procedures for addressing the identification, documentation, evaluation, segregation, disposition and investigation of all non-conforming device products as required by 21 CFR 820.90(a).

12) Procedures for component acceptance activities were not established, maintained and implemented as required by 21 CFR 820.80(a) & (b).

13) Failure to establish and maintain procedures for the control, approval and distribution of all documents as required by 21 CFR 820.40(a).

14) Failure to establish and maintain procedures for the control of device labeling activities as required by 21 CFR 820.120.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence with each requirement of the Act and the regulations. The specific violations noted in this letter and on the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food & Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction and/or civil penalties. In addition, federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering award of contracts.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the attention of Arthur S. Williams, Jr., Compliance Officer, Food & Drug Administration, New York District Office, 158 - 15 Liberty Avenue, Jamaica, New York 11433 – 1034, (718)662-5568.

Sincerely,

Jerome G. Woyshner
District Director
New York District